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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,515	07/29/2003	Mark L. White	ZPR 1027 US	8588

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,515	WHITE ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF PRELIMINARY AMENDMENT AND STATUS OF THE CLAIMS

1. The preliminary amendment filed 7/29/03 is acknowledged, entered and considered. Claims 1-12 are present for examination

CLAIMS OBJECTION

2. Claims 1-4 and 6-12 are objected in the recitation the acronym "BPI". Also, claims 11 and 12 in the recitation the acronyms "$rBPI_{23}$" and "$rBPI_{21}$", respectively. Use of the full terminology at least in the first occurrence of each of the acronyms would obviate this objection.

HEADINGS FOR STATUTORY BASIS OF DOUBLE PATENTING

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

REJECTION UNDER 35 U.S.C. § 101 FOR DOUBLE PATENTING

4. Claims 1, 2, and 8-12 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 of prior U.S. Patent No. 5,741,779. Both sets of claims are identical word for word. This is a double patenting rejection.

5. Claims 6 and 7 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 4 and 5 of prior U.S. Patent No. 5,935,930. Both sets of claims are identical word for word. This is a double patenting rejection.

HEADINGS FOR NONSTATUTORY DOUBLE PATENTING

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

DOUBLE PATENTING-NONSTATUTORY WITH A PATENT

7. Claims 3-7 are rejected under the under the judicially created doctrine of double patenting over claims 1-4 of U.S. Patent No. 5,741,779.

The subject matter claimed in the instant application is set forth in the'779 patent claims. The patent and the application claim common subject matter, as follows: The instantly claimed invention and the patent claim the administration of effective amount of BPI protein product alone and/or co-administration of a thrombolytic agent to treat thrombotic disorder which includes slowing clot formation in blood, enhancing clot dissolution in blood and enhancing reperfusion or reducing reocclusion in a subject. Both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the scope of the claims. The invention of the instantly claimed invention appears to be

broader in scope than that of the '779 patent which is specific because the instant invention's claims and/or encompasses the method for treatment of thrombotic disorder which includes slowing clot formation in blood, enhancing clot dissolution in blood and enhancing reperfusion or reducing reocclusion in a subject while the '779 patent claims the method for slowing clot formation in blood and a method for enhancing clot dissolution in blood. However, since both inventions are directed to antithrombotic materials and methods; it is conventional and would be within the purview of ordinary skill in the art to use or adapt either the broader scope or the specific because both procedures use the same techniques for treating a thrombotic disorder in a subject by administering an effective amount of BPI protein product alone and/or in combination with a thrombolytic agent. Therefore, both inventions are an obvious variation of the other since same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

8. Claims 1-5 and 8-12 are rejected under the under the judicially created doctrine of double patenting over claims 1-8 of U.S. Patent No. 5,935,930.

The subject matter claimed in the instant application is set forth in the'930 patent claims. The patent and the application claim common subject matter, as follows: The instantly claimed invention and the patent claim the administration of effective amount of BPI protein product alone and/or co-administration of a thrombolytic agent to treat thrombotic disorder which includes slowing clot formation in blood, enhancing clot

dissolution in blood and enhancing reperfusion or reducing reocclusion in a subject. Both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the scope of the claims. The invention of the instantly claimed invention appears to be broader in scope than that of the '930 patent which is specific because the instant invention's claims and/or encompasses the method for treatment of thrombotic disorder which includes slowing clot formation in blood, enhancing clot dissolution in blood and enhancing reperfusion or reducing reocclusion in a subject while the '930 patent claims the method for treating a subject suffering from a thrombotic disorder selected from the group consisting of a thrombosis, coronary artery thrombosis, cerebral artery thrombosis, etc.,. Thus, the '930 patent is specifically directed to treatment of thrombotic disorder such as various as claimed in claims 1 and 2. However, since both inventions are directed to antithrombotic materials and methods; it is conventional and would be within the purview of ordinary skill in the art to use or adapt either the broader scope or the specific because both procedures use the same techniques for treating a thrombotic disorder in a subject by administering an effective amount of BPI protein product alone and/or in combination with a thrombolytic agent. Therefore, both inventions are an obvious variation of the other since same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

9. Claims 1-12 are rejected under the under the judicially created doctrine of double patenting over claims 1-6 of U.S. Patent No. 6,107,280.

The subject matter claimed in the instant application is set forth in the'280 patent claims. The patent and the application claim common subject matter, as follows: The instantly claimed invention and the patent claim the administration of effective amount of BPI protein product alone and/or co-administration of a thrombolytic agent to treat thrombotic disorder which includes slowing clot formation in blood, enhancing clot dissolution in blood and enhancing reperfusion or reducing reocclusion in a subject. Both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the scope of the claims. The invention of the instantly claimed invention appears to be broader in scope than that of the '280 patent which is specific because the instant invention's claims and/or encompasses the method for treatment of thrombotic disorder which includes slowing clot formation in blood, enhancing clot dissolution in blood and enhancing reperfusion or reducing reocclusion in a subject while the '280 patent claims the method for slowing clot formation in blood by administering to a subject suffering from a thrombotic disorder or the method for enhancing clot dissolution by administering to a subject suffering from thrombotic disorder. Thus, the '280 patent is specifically directed to treatment of thrombotic disorder such as slowing clot formation in blood or enhancing clot dissolution in blood as claimed in claims 1 and 2. However, since both inventions are directed to antithrombotic materials and methods; it is conventional and would be within the purview of ordinary skill in the art to use or adapt either the broader

scope or the specific because both procedures use the same techniques for treating a thrombotic disorder in a subject by administering an effective amount of BPI protein product alone and/or in combination with a thrombolytic agent. Therefore, both inventions are an obvious variation of the other since same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

10. Claims 1-12 are rejected under the under the judicially created doctrine of double patenting over claims 1-6 of U.S. Patent No. 6,599,881.

The subject matter claimed in the instant application is set forth in the'881patent claims. The patent and the application claim common subject matter, as follows: The instantly claimed invention and the patent claim the administration of effective amount of BPI protein product alone and/or co-administration of a thrombolytic agent to treat thrombotic disorder which includes slowing clot formation in blood, enhancing clot dissolution in blood and enhancing reperfusion or reducing reocclusion in a subject. Both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the scope of the claims. The invention of the instantly claimed invention appears to be broader in scope than that of the '881 patent which is specific because the instant invention's claims and/or encompasses the method for treatment of thrombotic disorder which includes slowing clot formation in blood, enhancing clot dissolution in blood and enhancing reperfusion or reducing reocclusion in a subject while the '881 patent claims

the method for treating a thrombotic disorder that is not the result of an endotoxin-initiiated coagulation cascade wherein the thrombotic disorder is an acute vascular disease and the BPI protein product alone or in combination with thrombolytic agent is administered to slow clot formation or enhance clot dissolution. Thus, the '881 patent is specifically directed to treatment of thrombotic disorder that is not the result of an endotoxin-initiated coagulation cascade as claimed in claims 1 and 2. However, since both inventions are directed to antithrombotic materials and methods; it is conventional and would be within the purview of ordinary skill in the art to use or adapt either the broader scope or the specific because both procedures use the same techniques for treating a thrombotic disorder in a subject by administering an effective amount of BPI protein product alone and/or in combination with a thrombolytic agent. Therefore, both inventions are an obvious variation of the other since same procedure is used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

CLAIM REJECTION-35 U.S.C. § 102(b)

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/23434.

Under Summary of the Invention, the reference discloses that BPI protein product, namely a fusion protein comprising PBI or its biologically active fragment, can be used for the treatment of such conditions such as disseminated intravascular coagulation or thrombocytopenia (See e.g. page 5, line 25 to page 6, line 7). The prior art anticipates claim 3 as drafted because the claim is drawn to a method for treating a thrombotic disorder in a subject comprising administration of a pharmaceutically effective amount of a BPI protein product. It is noted that the claim language "thrombotic disorder" is very broad as defined in the instant specification on page 17, lines 26 to page 8, lines 9 since it encompasses various conditions associated with or resulting from thrombosis or a tendency towards thrombosis. Thus, all the elements of Applicant's invention with respect to claim 3 are clearly disclosed by the teachings of the reference cited above.

CLAIM REJECTION-35 U.S.C. § 102(e)

12. (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 3 is rejected under 35 U.S.C. 102(e) as being anticipated by Ammons et al (U.S. Patent No. 5,578,568).

Ammons et al disclose a method for treating a subject suffering from effects of intestinal ischemia/reperfusion, including cardiac and hemodynamic effects from a variety causes(See e.g., Summary of the Invention). The prior art anticipates claim 3 as drafted because the claim is drawn to a method for treating a thrombotic disorder in a subject comprising administration of a pharmaceutically effective amount of a BPI protein product. It is noted that the claim language "thrombotic disorder" is very broad as defined in the instant specification on page 17, lines 26 to page 8, lines 9 since it encompasses various conditions associated with or resulting from thrombosis or a tendency towards thrombosis. Thus, all the elements of Applicant's invention with respect to claim 3 are clearly disclosed by the teachings of the reference cited above.

To overcome the rejection above, Applicant has the burden of both clearly distinguishing the claimed invention as not being anticipated by the prior art; and then possibly demonstrating that it is nonobvious as well. Anticipation cannot be overcome by showings, comparisons or data of any kind; the discovery of a new property or use of a previous known invention, even if nonobvious from the prior art, cannot impart patentability to claims to a known composition.

CLAIMS REJECTION-35 U.S.C. § 103(a)

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/23434 or, alternatively over Ammons et al (U.S. Patent No. 5,578,568) taken with Bode et al (Zeitschrift fur Kardiologie, Vol. 82 (suppl. 2), pp. 125-128, 1993).

WO 93/23434 or Ammons et al as discussed above under the rejections 102(b) and (e), disclose the use of BPI to treat thrombotic disorders. The referenced prior art does not teach co-administration of BPI and thrombolytic agent. However, the

reference of Bode et al provides different examples teaching that combination thrombolytic therapy is advantageous in view of its higher efficacy and beneficial effects, such as improved dosing regiments as opposed to monotherapy (See e.g. abstract).

Further, as admittedly acknowledged in the instant specification on page 15, lines 3-8, it is known in the art that thrombolytic agents such as aspirin and plasminogen activator dissolve the clot and BPI enhances the dissolution activity of the thrombolytic agent. Furthermore, on pages 10-12, Applicant describes the advantages of concurrent administration or co-administration of BPI and thrombolytic agent in which Applicant has shown that it is desirable to co-administer BPI with thrombolytic agent for the purpose of decreasing the risk of adverse side effects associated with the use of thrombolytic agent (i.e., reduces toxicity). Thus, in view of these known desirable properties, one of ordinary skill in the art would have been motivated at the time the invention was made to co-administer BPI with thrombolytic agent for the purpose of obtaining the known and recognized functions and advantages thereof.

Therefore, it is the Examiner's position that it would have been *prima facie* obvious to one of ordinary skill in the art to have utilized a BPI product, which is effective in treatment of thrombotic disorders as taught by WO 93/23434 or Ammons et al, in combination or co-administration with thrombolytic agent, with the expectation that the combined therapy will be more effective, slows clot formation or enhances clot dissolution, less toxic and will require reduced doses of thrombolytic agent, as suggested by the secondary reference of Boden et al.

Also, with respect to claims 6 and 7, it would have been *prima facie* obvious to enhance reperfusion or reduce reocclusion by co-administering a BPI product and thrombolytic agent because BPI was proved to be effective in treatment of subjects suffering, especially, from the effects of reperfusion (See e.g., col. 2, lines 13-30 of Ammon's patent). Thus, in view of the above and in view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to employ a method for treating a thrombotic disorder (as broadly defined in the instant specification on page 17, lines 26 to page 8, lines 9 which encompasses various conditions associated with or resulting from thrombosis or a tendency towards thrombosis) including a method for slowing clot formation, a method for enhancing clot dissolution, a method of enhancing reperfusion or reducing reocclusion and a method for decreasing the dose of thrombolytic agent by administering a BPI protein product and/or co-administering a thrombolytic agent in a subject, absent of providing sufficient objective factual evidence or unexpected results to the contrary .

CONCLUSION AND FUTURE CORRESPONDANCE

14 No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

Mohamed/AAM

April 01, 2005